

Appl. No. ~~10/337,186~~

Reply to Office Action of April 30, 2003

09/882-781

REMARKS

This is a full and timely response to the final Office Action mailed January 20, 2004 (Paper No. 20040108). Reexamination and reconsideration in light of the above amendments and following remarks are courteously requested.

Claims 1-31 are pending in the application. Claims 8-15, 21-29 and 31 have been cancelled in view of the previously imposed restriction requirement and election of Formula I, as they are drawn to the non-elected invention of Formula II. Claims 1-7, 16-20 and 30 were examined to the extent that they encompassed the elected structure of $R_1\text{-CO-Arg-Trp-NH}_2$ (wherein R_1 is either alkyl or cycloalkyl), with Claims 1 and 16 being the independent claims. Therefore, due to this restriction requirement, Claims 2-5 and 16-20 have been cancelled as they are drawn to a non-elected invention. Claims 1, 6, 7, and 30 remain pending in the application. Claims 32-35 have been added and are supported in the specification at least at page 4, paragraphs 71-78, inclusive.

No new matter is believed to have been added.

Restriction Requirement

Applicant hereby affirms the election of claims classified as Group I, Formula I ($C_1\text{-C}_9\text{-alkyl-CO-Arg-Trp-NH}_2$) (wherein $C_1\text{-C}_9\text{-alkyl}$ includes $C_3\text{-C}_6\text{-cycloalkyl}$). Namely, Applicant elects Claims 1, 6, 7 and 30 drawn to Formula I, as elected. As such, Applicant has cancelled Claims 2-5 and 8-29 in response to Examiner's withdrawal of the non-elected invention, but reserves the right to prosecute at least these claims in a divisional application, which may be filed before the close of prosecution of the instant application.

Claim Rejections - 35 U.S.C. § 112

The Office Action has rejected Claims 1-7, 16-20 and 30 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Specifically, the Office Action states that the phrase "optionally" renders the claim indefinite because it is unclear whether the limitation following the phrase is part of the claimed invention. Applicant has amended Claim 1, and

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removed the phrase "optionally." Claim 16 has been cancelled. Therefore, in light of the above claim amendment, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. § 112 rejection.

Claim Rejections - 35 U.S.C. §§ 102 and 103

The Office Action rejects Claims 1-7, 16-20 and 30 under 35 U.S.C. 102(b) as allegedly being anticipated by Gloor, et al. (U.S. Patent Number 3,265,682). Claims 1, 6-7, and 30 remain pending in the application.

As repeatedly indicated by the courts, anticipation requires that all of the elements and limitations of the claims be found within a single prior art reference. There must be no difference between the claimed invention and the disclosure provided by the reference, as viewed by a person of ordinary skill in the field of the invention. Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991). Applicant respectfully submits that Gloor does not teach every element of the claims; therefore, the invention, as claimed herein, is not anticipated by Gloor.

Gloor does not disclose the formula elected by Applicant, namely alkyl-CO-Arg-Trp-NH₂. Specifically, nowhere in U.S. Patent No. 3,265,682, does Gloor discuss or disclose Tryptophan as a possible amino acid in its disclosed formula. Nor does Gloor disclose the use of an amino acid whose structure parallels or would indicate that of Tryptophan.

Applicant respectfully draws Examiner's attention to Column 7 of Gloor, where Gloor discloses a complete list of amino acids which Gloor deems relevant to or useful in its invention. Notably, Tryptophan is not included in the list, nor mentioned or disclosed at any other point in the patent. Therefore, Gloor does not teach every element of Applicant's claim 1, as amended. As such, the invention, as claimed, is not anticipated by Gloor.

Further, Gloor does not disclose the two amino acid structure of Arginine-Tryptophan as a possible amino acid combination in its formula. Nor does Gloor disclose the use of an amino acid combination whose structure parallels or would indicate that of the two amino acid structure of Arginine-Tryptophan. As the element of Applicant's claim 1, "n=2 and X₂ is Arg-Trp" is at the heart of the elected invention, Applicant's invention as embodied in claim 1 is not anticipated by Gloor.

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Because Claims 6-7 and 30 depend from Claim 1, and because independent Claim 1 is patentable over the citation of record, Claims 6-7 and 30 are also patentable for the reasons given with respect to the independent claim.

The Office Action rejects Claims 1-7, 16-20 and 30 under 35 U.S.C. 102(e) as allegedly being anticipated by Eisenbach-Schwartz, et al. (U.S. Patent Number 6,126,939), or in the alternative under U.S.C. § 103(a) as obvious over Eisenbach-Schwartz. Claims 1, 6-7, and 30 remain pending in the application.

As noted above, anticipation requires that all of the elements and limitations of the claims be found within a single prior art reference. There must be no difference between the claimed invention and the disclosure provided by the reference, as viewed by a person of ordinary skill in the field of the invention. Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991). Applicant respectfully submits that Eisenbach-Schwartz does not teach each and every element of the claims; therefore, the invention, as claimed herein, is not anticipated by Eisenbach-Schwartz.

As a preliminary matter, Eisenbach-Schwartz particularly teaches an anti-inflammatory dipeptide or tripeptide selected from a group consisting of hundreds of possible di- and tripeptides. Merely because one of the dipeptides disclosed as useful to treat inflammation is Arg-Trp does not automatically render Applicant's invention anticipated by Eisenbach-Schwartz. In order for Applicant's invention to be anticipated by Eisenbach-Schwartz, the exact formula must be disclosed in the patent. Examiner states that Eisenbach-Schwartz discloses the dipeptide of Arg-Trp-NH₂. However, as Examiner acknowledges, this alone, is not sufficient to anticipate Applicant's invention because it does not anticipate each and every element of Claim 1.

Examiner asserts that Eisenbach-Schwartz also sets forth derivatives of the disclosed dipeptides comprising alkylation of the dipeptide. Examiner fails to point out where Eisenbach-Schwartz discloses alkylation that results in Applicant's formula of alkyl-CO-Arg-Trp-NH₂. The only reference to alkylation of dipeptides disclosed in Eisenbach-Schwartz results in the presence of the alkyl group on the N terminal of the dipeptide, namely "-CO-N-(alkyl)-" as disclosed in Column 9 of Eisenbach-Schwartz.

Applicant's invention clearly claims a dipeptide with an alkyl or cycloalkyl on the

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carboxyl terminal of the dipeptide, as represented by the formula: alkyl-CO-Arg-Trp-NH₂. Therefore, Eisenbach-Schwartz does not teach each and every element of Applicant's invention. Thus, Eisenbach-Schwartz does not anticipate Applicant's invention.

Furthermore, Claim 1, as amended, specifically claims that "the antimicrobial peptide inhibits the growth of a microbe selected from the group consisting of bacteria, archaea, fungi, algae, protozoa, multicellular parasites and viruses." Eisenbach-Schwartz particularly and specifically teaches the treatment of inflammation. No where does Eisenbach-Schwartz discuss or disclose that Applicant's invention, in particular, Formula I as now claimed (alkyl-CO-Arg-Trp-NH₂), has antimicrobial properties and is useful to inhibit or terminate the growth of a variety of microbes.

With respect to Examiner's alternative rejection under 35 U.S.C. 103(a), "in proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art." In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). "[I]dentification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant." In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000).

An adequate showing of motivation to combine requires "evidence that 'a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" Ecolchem, Inc. v. Southern Calif. Edison Co., 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075 (Fed. Cir. 2000) (quoting In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998)). "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight." In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

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Applicant respectfully disagrees with Examiner that somehow Applicant's invention is obvious in light of Eisenbach-Schwartz. Notably, Eisenbach-Schwartz teaches that alkylation of a dipeptide, and presumably, according to Examiner's interpretation of Eisenbach-Schwartz, a dipeptide comprising Arg-Trp, results in the alkylation of the N-terminal. Thus, Eisenbach-Schwartz actually teaches away from Applicant's invention of a dipeptide comprises Arg-Trp with an alkyl or cycloalkyl group present on the carboxyl terminal of the dipeptide.

Furthermore, Claim 1, as amended, specifically claims that "the antimicrobial peptide inhibits the growth of a microbe selected from the group consisting of bacteria, archaea, fungi, algae, protozoa, multicellular parasites and viruses." Eisenbach-Schwartz particularly and specifically teaches the treatment of inflammation. Eisenbach-Schwartz does not teach that any of the formulae disclosed have any antimicrobial properties, nor does it provide any motivation for using any of the formulae disclosed for antimicrobial applications. Thus, Applicant's invention is clearly not obvious in light of Eisenbach-Schwartz.

Further, because Claims 6-7 and 30 depend from Claim 1, and because independent Claim 1 is patentable over the citation of record, Claims 6-7 and 30 are also patentable for the reasons given with respect to the independent claim.

In light of the above amendments and remarks, reconsideration and withdrawal of the §§ 102 and 103 rejections are therefore, respectfully requested.

The other art of record is also not understood to disclose or suggest the inventive concept of the present invention as defined by the claims.

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Conclusion

Applicant submits that the present application is in condition for allowance. Favorable reconsideration and withdrawal of the rejections set forth in the above-noted Office Action, and a Notice of Allowance are requested.

If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the below-listed number.

Respectfully submitted,

Arizona Board of Regents, for and on behalf of
Arizona State University

July 20, 2004

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